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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,564	01/27/2000	PASCAL CLAUDE MICHEL LOUVEL	P1047/20008	6103

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EXAMINER

PULLIAM, AMY E

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 01/02/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/402,564

Applicant(s)

LOUVEL ET AL.

Examiner

Amy E Pulliam

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Receipt is acknowledged of the Request for Extension of Time and the Notice of Appeal, both received August 2, 2001, as well as the Request for an RCE, received September 26, 2001.

Claims 5 and 6 have been canceled and new claims 7 and 8 have been added.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/14058 to Oshlack *et al.* (hereinafter WO '058). WO '058 teaches a sustained release dosage form comprising a plurality of microparticles produced via melt extrusion techniques (abstract), and WO '058 also discusses the extruder used to make the formulation. WO '058 teaches that the active ingredient in the formulation is in a matrix including a hydrophobic material, such as alkylcelluloses and acrylic polymers, and a hydrophobic carrier (p 6, l 13-30). However, WO '058 further teaches that a plasticizer can also be added to help with the extrusion process (p 10, l 21-26). WO '058 also teaches a method for preparing their formulation, which involves blending the drug with the matrix

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ingredients, heating the blended mixture, placing the mixture in the extruder, extruding the strands, then dividing the strands into the desired pieces, such as pellets (p 7, l 15-30, and claim 18). WO '058 also teaches that the extruded materials can be cut into multiparticulates by any means known in the art, and they further teach that the multiparticulates can be compressed into tablets (p 8, l 1-2). Lastly, WO '058 teaches that the exit port of the extruder can be any desired shape, in order to make the multiparticulates the desired shape and size (p 17, l 23-25). It is the position of the examiner that this disclosure reads on the method of making particles as claimed by applicant.

Applicant's arguments have been considered but are not found to be persuasive. Applicant argues that the above rejection does not apply to the new method claim because the cited art does not teach a maturation step outside the extruder. The newly added maturation step states that the mixture is maintained at a temperature in the range from 20 – 70° C, from 30 minutes to 150 hours, causing the maturation of the mixture. Applicant's further argue that there is evidence in the instant specification to show that there is a patentable difference between the instant claims and the prior art. Applicant has directed the examiner to examples 1 and 2 of the specification. Upon careful examination of these examples, the examiner notes several things. First, applicant has compared three different sets of samples, matured at room temp (or 20°), 40° and 70°. Each of these three samples falls within the temperature range claimed by applicant in the new claims. Therefore, it is not clear to the examiner what is being demonstrated with these examples. Second, the examiner looks to table I on page 15

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of applicant's specification. Upon careful examination of the table, and absent any statistical analysis, the examiner does not find a significant between the values of the A group versus the values of the B and C groups, particularly after several hours. For instance, after 4 hours, A2 has released 74.5%, while C1 has released 70.1%. Additionally, after 5 hours, B3 has released 61.5% and C3 has released 61.1%. It appears that there is no statistical or significant difference between these values.

Furthermore, applicant's added maturing step does not actually require heating, as 20°, which is average room temperature, is the lower end of the claimed range. Therefore, the rejection over the new method claim (claim 7) is maintained.

Claim Rejections - 35 USC § 103

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over WP 96/14058 to Oshlack *et al.* as discussed above, and in view of the following comments. Although WO '058 does not teach that the particles are spheroidal, they do teach that the exit port of the extruder can be any shape desired. They further teach that they want to eliminate the spheronization step, which is stated by applicant as well, and it is the position of the examiner that by allowing the exit port of the extruder to be any shape so that the multiparticulates can be of any shape, this allows the exit port to be a shape that would form spheroidal particulates. Further, although WO '058 does not specifically refer to a maturing step, it is the position of the examiner that the heating step prior to extrusion, which is discussed by WO '058, reads on applicant's claimed

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maturing step. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments have been fully considered but are not found to be persuasive. Applicant argues that the heating step relied upon in WO '058 does not teach the maturing step of applicant's claimed process. However, the examiner respectfully disagrees. WO '058 does teach a heating step prior to the extrusion, and applicant's claimed maturing step is simply a heating step with a defined time and temperature. Applicant further argues that the heating step relied upon by the examiner is simply a normal step carried out in an extrusion method, and applicant further argues that this step takes place within the extrusion machine. However, the examiner disagrees as there is no evidence to prove that this heating step, discussed by the prior art, takes place inside the extrusion machine.

Applicant has further argued that there is evidence of patentable differences between the prior art and the instant claims, said changes due to the maturation step. However, as discussed above, there are problems with the evidence applicants have relied on, as all the data falls within the range claimed by applicant (heated to 20-70° C). Therefore, there is no comparative data. Additionally, it is the position of the examiner that there is no statistical or significant difference between the samples kept at room temperature, versus the samples heated to 40° or 70° C. Lastly, applicants have included heating to 20° C as part of the claimed range, and this temperature is equal to

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average room temperature which is actually not a heating step at all. Therefore, applicant's current claim language does not require that the mixture be heated.

Lastly, applicant argues that the instantly claimed apparatus is not rendered obvious because the prior art does not teach an extruder comprising a tool for chopping particles as defined by the instant claim. The examiner respectfully disagrees. The cited art teaches that their process eliminates the spheronization step (p 5, l 25). Additionally, the cited art teaches that the extrudate is cut by blades after the melt extrusion process. It is the position of the examiner that the cutting tool claimed by applicant is the equivalent to a typical cutting blade at the exit of the extrusion machine. Furthermore, the examiner directs applicants attention to page 17, lines 28-30 of the cited reference. Here, it is taught that the multiparticulate system can be in the form of granules, spheroids, or pellets, depending on the extruder exit orifice. Therefore, absent any evidence to the contrary, it is the position of the examiner that the apparatus of the cited reference renders applicant's cited apparatus obvious, as the cutting step disclosed in the reference also renders spheroids, and therefore, although it is not specified, it must be an equivalent blade setup.

Conclusion

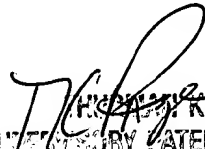
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

aep
December 26, 2001


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600